MAY 13 2014

510(k) SUMMARY

510(k) Notification K 140942

GENERAL INFORMATION

Applicant:
Total Joint Orthopedics
1567 E. Stratford Avenue
Salt Lake City, UT 84106
United States
Phone: 801-486-6070
FAX: 801-486-6117

Contact Person:
Jean M. Wheeler
Product Development Engineer
Total Joint Orthopedics
1567 E. Stratford Avenue
Salt Lake City, UT 84106
United States
Phone: 801-486-6070
Fax: 801-486-6117

Date Prepared: April 11, 2014

DEVICE INFORMATION

Trade/Proprietary Name:
Klassic™ Knee Tibial Stem Extension

Generic/Common Name:
Knee prosthesis, tibial stem extension

Classification:
21 CFR §888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

Product Code:
JWH

510(k) SUMMARY

PREDICATE DEVICE(S)

The Klassic Knee Tibial Stem Extension is substantially equivalent in intended use, design, function, performance testing to the following predicate devices:

- Klassic Knee System – Total Joint Orthopedics K112906
- Universal Stem Extensions – DePuy K063633
- Triathlon TS Knee System – Stryker Orthopedics K070095

INTENDED USE

The Klassic Knee Tibial Stem Extension is intended for use with the Klassic Knee System. The Klassic Knee System is intended for prosthetic replacement with the use of bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
- Patients with failed previous surgery where pain, deformity, or dysfunction persists
- Correctable varus-valgus deformity and moderate flexion contracture
- Revision of a previously failed knee arthroplasty
- Patients who require a total knee replacement

PRODUCT DESCRIPTION

The Klassic Knee Tibial Stem Extension is a modular component designed for use with the Klassic Knee System Tibial Baseplate to provide the user with options for stemming the Tibial Baseplate where additional distal fixation is desired. The Stem Extension is fully compatible with the predicate Klassic Knee System and offered in lengths up to 150mm. The Klassic Knee Tibial Stem Extension is manufactured from titanium alloy and features a threaded connection which allows for attachment to the Klassic Knee System Tibial Baseplate.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Klassic Knee Tibial Stem Extension were compared to predicate devices to serve as a basis for determining substantial equivalence. The Klassic Knee Tibial Stem Extension is similar in device design, material of manufacture, sterilization and size offerings.

510(k) SUMMARY

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Non-clinical bench testing was conducted on the Klassic Knee Tibial Stem Extension to support a determination of substantial equivalence to the predicate devices. Non-clinical bench testing was based off of guidance from:

- ASTM F2083-12 Standard Specification for Knee Replacement Prosthesis
- ASTM F1814-97(2009) Standard Guide for Evaluating Modular Hip and Knee Joint Components
- ASTM F1800-12 Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements

The performance bench testing for the Klassic Knee Tibial Stem Extension evaluated the use of the worst case geometry of the subject device with the Klassic Knee System in fatigue and the impact of fatigue loading on the modular connection mechanism of the device. Specifically, the following tests were conducted:

- Cantilever Bending Fatigue Testing
- Post Fatigue Fretting-Corrosion Analysis
- Analysis of the Integrity of the Modular Connection

All bench testing demonstrates the Klassic Knee Tibial Stem Extension is equivalent in regards to safety and efficacy, is suitable for use in Total Knee Replacement and is substantially equivalent to predicate devices.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Klassic Knee Tibial Stem Extension. The Klassic Knee Tibial Stem Extension is similar to the predicate devices based on technological characteristics, design, material, non-clinical performance testing, sterilization and intended use. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Klassic Knee Tibial Stem Extension is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

Total Joint Orthopedics, Incorporated
Ms. Jean M. Wheeler
Product Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

Re: K140942
Trade/Device Name: Klassic™ Knee Tibial Stem Extension
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: April 11, 2014
Received: April 14, 2014

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140942

Klassic™ Knee Tibial Stem Extension:

Indications For Use:

The Klassic™ Knee Tibial Stem Extension is intended for use with the Klassic™ Knee System. The Klassic™ Knee System is intended for prosthetic replacement with the use of bone cement in treatment of the following:

- Patient conditions of non-inflammatory degenerative joint disease (NIDJD): avascular necrosis and osteoarthritis
- Patient conditions of inflammatory joint disease (IJD): rheumatoid arthritis
- Patients with failed previous surgery where pain, deformity, or dysfunction persists
- Correctable varus-valgus deformity and moderate flexion contracture
- Revision of a previously failed knee arthroplasty
- Patients who require a total knee replacement

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE: CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices